Tetrachlorvinphos (TCVP) Updated Risk Assessment and Petition Response Path Forward

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Briefing Objective

- Determine whether to cancel TCVP pet products or deny NRDC petition to do so
  - Discuss risks of exposure to TCVP pet products
  - Discuss potential rationale to deny petition

Outline

- Use and Usage
- Benefits and Alternatives
- Environmental Justice Considerations
- Risk Assessments
- Petition Pathway Options
- Appendix
  - Comments on DRAs
  - Litigation History

Use

- TCVP is an organophosphate (OP) insecticide; the mode of action is neurotoxicity via acetyl cholinesterase (AChE) inhibition.
- There are two technical registrants: Hartz and Bayer, and about 40 end-use registrations.
- Registered uses are on livestock and domestic animals or as a perimeter treatment. There are no crop uses.
- The sole technical registrant for pet products (cats and dogs) is Hartz. There are 16 end-use pet product registrations.
  - Other sellers and distributors in addition to Hartz.
  - Pet products include flea and tick collars, powders, and pump sprays.

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Hartz may be the only registrant, but there may be other sellers/distributors. Brands include Zodiac, Adams. May be Gardona products, voluntarily cancelled last year?

Hartz has 11 product registrations, but there are 16 total pet products; 4 might be "me-too" and Hartz changes the size of some of it's collars

Usage

- Pet insecticide products were a $1.4 billion industry in 2016, with projected sales to approach 1.7 billion in the next year
- According to survey by American Veterinary Medical Association, in 2011, Approximately 90% of dog owners and 70% of cat owners purchase pet insecticides
  - Primarily tick and flea products
  - Mainly liquids; collars and powders account for <10% of sales ($)
- However, people may use more than one type of product
  - 25% of owners purchase collars
  - Almost 10% purchase powders

Information from a 2017 Assessment. Data on usage of pet products in 2016 are now available; BEAD can probably update parts of the assessment by end of May.

Benefits and Alternatives

- Potential Alternatives to TCVP Collars
  - Collars containing amitraz and deltamethrin (dogs only), flumethrin/imidacloprid and scented oils (dogs and cats)
  - Topical (liquids) contain pyrethroids, fipronil, imidacloprid, indoxacarb, pyriproxyfen – usually in combination

- TCVP-containing collars typically cheaper than alternatives
  - Accounting for duration of control, may be $5-6/month more than TCVP collars
  - Some essentially the same cost, some > $20/month more

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Environmental Justice

- Unclear whether impact from cancellation would be greater on low income/marginal households
  - Use of pet collars/powders somewhat less likely among pet owners in single family dwellings
  - Use of pet collars/powders somewhat more likely if family income < $25,000/year – but also if income > $100,000/year
- Complex issue with contradictory factors
  - Cancelling: impact may be relatively greater on low income households
  - Not cancelling: exposure may be relatively greater on low income households

Human Hazard Characterization

- Risk assessment endpoints based on red blood cell AChE inhibition
  - Benchmark dose modeling (BMD) used to derive PODs
  - 10X FQPA SF retained for populations of concern
- Classified as a Possible Human Carcinogen (Group C): $Q1^* = 1.83 \times 10^{-3}$ $(mg/kg/day)^{-1}$
- Given the timeframe, the September SAP will not contribute to the TCVP risk assessment

Dietary Exposure and Risk Assessment

- Dietary Non-cancer
  - Population subgroup of concern Children 3-5 at 180% aPAD and 120% ssPAD
  - Refinements made using PDP data where available
    - Anticipated residues used for chicken skin
  - Drinking water refinements were included
- Dietary Cancer
  - Cancer Risk Estimates at 10^{-7}

Summary of Residential Risk Estimates – Pet Products (LOC = 1000)

Dusts/Powders	Trigger-Pump/Sprays	**Pet collars** – no residential handler risks; post-application risks identified (X = risks identified)			
		Products		**Use of Davis data**	**Use of Hartz data**
No residential handler risks Post-application risks for all registered products 47000-123 2596-78 2596-79 67517-82	No risks (handler or post-application) identified 2596-126 2596-140 2596-125	2596-49	Cat	X	X
		2596-50, 62	Small Dog	X	
			Large Dog	X	
		2596-63	Small Cat	X	X
			Large Cat	X	
		2596-83	Small Cat	X	X
			Large Cat	X	X
		2596-84	Small Dog	X	X
			Large Dog	X	
		2596-139	Cat	X	
			Dog	X	X
		11556-164	Dog	X	
		11556-165	Cat	X	

Potential cancer risks of concern from pet collars:

Using Davis study data: Cancer risk estimates range from 10^{-6} to 10^{-5}

Using Hartz study data: Cancer risk estimates range from 10^{-7} to 10^{-6}

Some me-too products…

Residential Handler Risk Assessment

- Residential handler exposures expected from use of pet collars, dusts, and pump/trigger sprays

- Non-Cancer Risk Estimates
  - Adult inhalation only (no dermal POD); LOC = 300
  - No risks of concern identified for all pet products (all MOEs ≥ 3,200)

- Cancer Risk Estimates range from 10^{-9} to 10^{-7}

Residential Post-application Risk Assessment

- Residential post-application exposures expected from contact with pets previously treated with collars, dust/powders, or pump/trigger sprays
- Exposure data issues related specifically to pet collars
- In NRDC opening brief from 2015, cited label language: *"as the collar begins to work, a fine white powder will appear on the surface."*
- Up to this point, HED had been assessing collars as liquid formulations, not dust formulations
- No exposure data available for collars to determine formulation type and/or relative fractions of liquid/dust available
- In Dec. 2016, HED began using ratio approach (e.g., % liquid:% dust) to address formulation uncertainty and requested data from pet collar registrants
- After 2016 TCVP risk assessment, started discussions with Hartz about this uncertainty and need for data

Residential Post-application Risk Assessment

- DCI issued in June 2019 to address formulation uncertainty
  - DCI was for a "dust torsion" study which is conducted to measure the amount of solids released from a pet collar when the collar is exposed to extreme mechanical torsion (twisting) and stress
  - Provides refinement for assumption of ratio of liquid:dust releasing from collar
- A TCVP pet collar dust torsion study was submitted by Hartz in August of 2019 in response to DCI
- In addition, Hartz submitted a residue transfer study to determine the amount of TCVP residues (solid or liquid) which transfer over time from the fur of an animal treated with the pet collar to the exposed person

Residential Post-application Risk Assessment

- Children 1 to <2 years incidental oral only (no dermal POD); LOC = 1000

- Dusts/Powders (4 products; for both cats and dogs)
  - Risks of concern identified
  - MOEs range from 98- 640
  - Cancer risk estimates range from 10^{-7} to 10^{-6}

- Pump/Trigger Sprays (3 products; for both cats and dogs)
  - No risks of concern identified
  - MOEs range from 1,600 – 15,000
  - Cancer risk estimates are all 10^{-7}

Aggregate Assessment

- Non-cancer
  - Cannot make non-cancer aggregate safety finding at this time
    - Acute aggregate = acute dietary (food + water) assessment = risks of concern
    - Steady-state aggregate = dietary (food + water) + residential = risks of concern
- Cancer
  - Aggregate cancer risk estimates for handlers are in the 10^{-7} to 10^{-6} range and for post-application are in the 10^{-7} to 10^{-5}.

Occupational Risk Assessment

- Occupational handler exposures expected for livestock, kennel, outdoor perimeter, and pet treatments
- Handler - non-cancer
  - Inhalation only; LOC = 300
  - 172 occupational handler exposure scenarios assessed
  - The majority (142) are not of concern either at baseline or with currently required PPE (i.e., respirators)
  - 30 scenarios are of concern and include certain handheld equipment scenarios, fogging scenarios, and dust products.
    - 19 are not of concern with consideration of increasing levels of respiratory protection
    - 11 remain of concern despite the addition of respiratory protection or engineering controls
- Handler - cancer
  - Occupational handler range: 10^{-10} to 10^{-4}

Draft Ecological Risk Assessment

- TCVP registered for use as larvicide in manure. Residues can pass through livestock and remain active in manure.
- The ecological DRA identified risks to birds, mammals, and freshwater invertebrates.
- Based on available data, risk estimates would exceed acute risk LOC for adult bees from contact exposure.
- Tier 1 suite of laboratory-based studies of honey bees is incomplete
  - Missing acute/chronic oral toxicity for adult and larval bees.
- EPA received comments on the EFED DRA from the USDA, Bayer, and Centers for Biological Diversity (CBD).

The ecological DRA identified risks to birds (chronic RQs: 0.5 – 87), mammals (acute RQs <0.1 – 9.2; chronic RQs 0.05 – 8.35), and freshwater invertebrates (acute RQs 0.34 – 0.8; chronic RQs 5 – 9).
DRA did not quantify risks to terrestrial invertebrates; however, based on available data terrestrial invertebrate risk (adult acute contact RQ 0.078 - 0.77).

The Tier suite of laboratory-based acute and chronic toxicity studies with adult and larval bees is incomplete as only adult acute contact toxicity data are currently available for TCVP. Although the compound does not have any agricultural uses and is not applied directly to plants, the pass-through of residues in manure represents a potential route of exposure for ground-nesting non-Apis bees.

Submission of a complete set of Tier 1 honey bee toxicity data is needed for TCVP to fully assess Tier 1 risk to individual bees. Pending the results of Tier 1 studies, additional higher-tier data (e.g., nectar and pollen residue data and/or semi-field studies at environmentally relevant concentrations) may be useful for refining the understanding of potential exposure of bees from registered uses, and the extent of risk at the colony level.

Litigation and Response Pathways

- Option 1: Grant the petition
- Option 2: Partial grant+denial
- Option 3: Deny the petition

Litigation and Response Pathways

- Option 1: Grant the petition
  - Cancel all pet uses, would likely be a Notice of Intent to Cancel (NOIC)
  - The NOIC will identify the risks and benefits relevant to the action that EPA is proposing to take, and the conclusory rationale for the action.
    - The "benefits" side cannot be ignored.
    - EPA will also need to figure out how broad or narrow the cancellation rationale will be.
  - The draft NOIC must go for review to the SAP and USDA before it can be published. **This is the point at which we would have "initiated cancellation" per the Court's order, so this is what would need to happen by July 21**.

Talk to Hartz. If they're willing to voluntarily cancel, we generally have more flexibility the earlier a cancellation request is received. If they are willing to cancel, we'd need to figure out whether we'd allow a phase-out and if so, how long a phase-out we'd tolerate; what to do with existing stocks at all three levels (in registrants hands, other sale and distribution, use); and if we'd wish to have any modifications to terms of sale or use while sale or use is still allowed. If Hartz submits a 6(f) request, perhaps all we would need to do by July 21 (the 90-day deadline) is let the court know that we're processing (and intend to act on) the request, the granting of which would moot out the petition.

. Generally, we like to identify witnesses and talk to them before drafting the notice – that might not be possible here, but not doing so will add potential risks/complications for the process.

OPP and OGC draft the NOIC; similar to a PID, but more like a proposed rule-making
Identify risks and benefits relevant to action
One issue may be whether benefits matter to the decision or whether FQPA standard is appropriate
Set up SAP; prepare statements
Draft NOIC sent for review to the SAP and USDA (possibly HHS, given residential concerns). This is the point at which we would have "initiated cancellation" per the Court's order, so this is what would need to happen by July 21.
NOIC published for comment; revised and Final Cancellation Order is issued
Registrant may request a hearing, at which point witness statements (based on NOIC and any subsequent analyses) are drafted
Hearing with Administrative Law Judge
If ALJ rules for EPA, registrant can appeal to federal court

Litigation and Response Pathways

- Option 2: Partial grant+denial
  - Retain the uses that currently do not exceed the agency's level of concern, work with registrant for voluntary cancellations of the others
    - For example, retain trigger pump pet sprays but work with Hartz to cancel dust powders and selected pet collars.
  - If Hartz announces that they will not voluntarily cancel products for which potential risks were identified, the EPA will move to the cancellation path for those products.
  - Potentially resource-intensive to develop a dual-type of response

Talk to Hartz. If they're willing to voluntarily cancel, we generally have more flexibility the earlier a cancellation request is received. If they are willing to cancel, we'd need to figure out whether we'd allow a phase-out and if so, how long a phase-out we'd tolerate; what to do with existing stocks at all three levels (in registrants hands, other sale and distribution, use); and if we'd wish to have any modifications to terms of sale or use while sale or use is still allowed. If Hartz submits a 6(f) request, perhaps all we would need to do by July 21 (the 90-day deadline) is let the court know that we're processing (and intend to act on) the request, the granting of which would moot out the petition.

Litigation and Response Pathways

- Option 3: Deny the petition
  - Even with additional registrant data, the revised risk assessment currently indicates that potential risks of concern have been identified for some residential pet products
  - This option does not appear feasible with the information from the revised HHRA
  - Steps:
    - Draft response
    - Get management approval
    - See 2014 Denial for example

Petition Pathway Forward

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- OGC has requested management decision on petition response by May 13
  - As much time as possible is needed for development. A decision for this path would need to be made and started by mid-May
  - Option 1: Fully grant the petition
  - Option 2: Partial grant of the petition; deny petition for products which potential risks were not identified
  - Option 3: Deny the petition

Next Steps

- Prepare and issue response to NRDC's 2009 petition by July 21
- Revised Human Health Draft Risk Assessment scheduled for Q3 (June)
- Proposed Interim Decision scheduled for FY 2020 Q1

Appendix

- Litigation History

Comments on Draft Risk Assessments

- In 2009, the agency received approximately 8,600 form letters as part of a mass campaign supporting NRDC's petition to ban TCVP and propoxur pet products.
  - EPA also received a comment from The Humane Society of the United States that supported the petition and a comment from one TCVP registrant that opposed the petition.
- A total of 17 comments were received for the registration review docket
  - Comments from Bayer, Hartz, NRDC, USDA, and CBD
- The docket also includes responses to comments on other OP documents:
  - Responses to EDSP comments on preliminary OP HH DRAs
  - Responses to comments related to applying the FQPA 10X SF for OPs
  - Responses to ORE and dietary comments on preliminary OP HH DRAs

Litigation History

- April 23, 2009, NRDC filed a petition for EPA to cancel all pet uses for TCVP
- November 6, 2014: EPA denied the petition after conducting a revised risk assessment to evaluate residential exposure for all TCVP pet products
- January 5, 2015: NRDC filed a Petition for Review of EPA's denial in the 9th Circuit Court of Appeals. The DRAs are published in the docket on January 20, 2015
- December 21, 2016: The EPA issued a revised human health risk assessment for TCVP, indicating potential risks of concern for children, but highlighting major uncertainties in the assessment (e.g., liquid vs. solid formulation of active ingredient in pet collars)
- March 21, 2017: The EPA issued a letter in response to NRDC's 2009 cancellation petition stating that the agency intends to address any risk mitigation issues in the course of registration review

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DRAs were published to the docket January 20, 2015

New DRA included Davis study

Litigation History

- From 2017 to 2018, EPA communicated with the registrant, Hartz Mountain Corporation, regarding the development of new pet collar data to address the composition and ratio (% liquid vs. dust) of material coming off pet collars
- May 29, 2019: NRDC filed a lawsuit seeking a court order for EPA to respond in full to the 2009 petition based on "unreasonable delay"
- September 9, 2019: The agency filed a Declaration and Answering Brief in response to the May 29, 2019 unreasonable delay suit, requesting that the Court allow until September 2021 to complete its response
- February 2020: Oral arguments were presented
- April 22, 2020: The Ninth Circuit Court ruled that EPA must respond to the petition within 90 days

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June 3, 2019: The EPA issued a data call-in (DCI) requiring Hartz to submit a composition "torsion" study to address the composition of pet collars.
August 28, 2019: Hartz provided a response to the DCI committing to conducting the torsion study.